

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13093



0 - FRONT

Triage unit sequence #	89011
	13093

A. Patient information

1 Patient identifier	2 Age at time of event: 48 or Date of birth: [redacted]	3 Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4 Weight 205 lbs or kgs
----------------------	---	--	-------------------------------

B. Adverse event or product problem

1 <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2 Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input checked="" type="checkbox"/> other
3 Date of event (mo/day/yr) 8/20/98	4 Date of this report (mo/day/yr) 8/26/98

5 Describe event or problem

Medications, herbal when mixed - cause extreme photo sensitive reaction

6 Relevant tests/laboratory data, including dates

none needed

REC'D.

SEP 09 1998

MEDWATCH CTU

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Hay fever med- Sinu-stop x4

Allopurinol daily

Aspirin - 2mg

CTU 89011

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)		3 Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 Sinu-stop		#1	
#2 HERBAL LIFE WT LOSS Program		#2	
2 Dose, frequency & route used		4 Diagnosis for use (indication)	
#1 DAILY x 4		#1 Hay fever symptoms	
#2		#2 WEIGHT LOSS	
6 Lot # (if known)		7 Exp. date (if known)	
#1		#1	
#2		#2	
9 NDC # (for product problems only)		5 Event abated after use stopped or dose reduced	
#1		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
8 Event reappeared after reintroduction		10 Concomitant medical products and therapy dates (exclude treatment of event)	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply			

D. Suspect medical device

1 Brand name		Operator of device	
2 Type of device		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other	
3 Manufacturer name & address		4 Expiration date (mo/day/yr)	
6 model #		7 If implanted, give date (mo/day/yr)	
catalog #		8 If explanted, give date (mo/day/yr)	
serial #			
lot #			
other #			
9 Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mo/day/yr)			
10 Concomitant medical products and therapy dates (exclude treatment of event)			

E. Reporter (see confidentiality section on back)

1 Name, address & phone #			
000001			
2 Health professional?	3 Occupation	4 Also reported to	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	CMA	<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	
5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>			



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report **SERIOUS** adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS
Hubert H. Humphrey Building,
Room 721-B
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: PRA

and to:
Office of Management and
Budget
Paperwork Reduction Project
(0910-0230)
Washington, DC 20503

Please do NOT
return this form
to either of these
addresses.

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business

Penalty for Private Use \$300

BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH

The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

000002